PCT/JP2003/008305

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference OP2003-027	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/008305	International filing date (*day/month/year*) 30 June 2003 (30.06.2003)	Priority date (*day/month/year*) 01 July 2002 (01.07.2002)
International Patent Classification (IPC) or national classification and IPC C07K 16/18, C12N 5/16, 15/13, A61K 39/395, A61P 31/18		
Applicant OKADA, Hidechika		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) disc 1 _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09 January 2004 (09.01.2004)	13 September 2004 (13.09.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMI[redacted] REPORT ON PATENTABILITY

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[redacted]CT/JP03/08305

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

The technical feature common to claims 1, 2 and 6 is a "human antibody (hereinafter, referred to as "this antibody") that specifically recognizes HIV-infected cells and induces apoptosis."

As a result of the search, however, this antibody is disclosed in document 1 [The Polypeptide Encoded by the cDNA for Human Cell Surface Antigen Fas Can Mediate Apoptosis, (N. Ito, et al.), Cell, 1991, Vol. 66, No. 2, pages 233-243], document 2 [WO, 9722361, A1 (Hidechika Okada), 26 June, 1997 (26.06.97), the claims, examples], document 3 [EP, 510691, A1 (Osaka Bioscience Institute), 28 October, 1992 (28.10.92), entire document], and document 4 [The State-of-the-Art Apoptosis Experiment Methods, edited by Yoshihide Tsujimoto, Separate Volume of Experimental Medicine, Bio Manual Up series, 25 March, 1997 (25.03.97), pages 112-117], and so it does not appear to be novel.

This antibody, therefore, is not beyond the scope of the prior art, and so is not a special technical feature in the sense of the second sentence in PCT Rule 13.2.

Accordingly, the above-mentioned claims do not have any matter in common.

There are no other possible special technical features common to them in the sense of the second sentence in PCT Rule 13.2, and there is no relationship in the sense of the provisions of PCT Rule 13 found among the different subject matters of the said claims.

Accordingly, the subject matters of claims 1, 2 and 6 clearly do not satisfy the requirement of unity of invention.

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos. _____.

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4-7	YES
	Claims	1-3	NO
Inventive step (IS)	Claims	4-7	YES
	Claims	1-3	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: The Polypeptide Encoded by the cDNA for Human Cell Surface Antigen Fas Can Mediate Apoptosis, (N. Ito, et al.), Cell, 1991, Vol. 66, No. 2, pages 233-243
Document 2: WO, 9722361, A1 (Hidechika Okada), 26 June, 1997 (26.06.97)
Document 3: EP, 510691, A1 (Osaka Bioscience Institute), 28 October, 1992 (28.10.92)
Document 4: The State-of-the-Art Apoptosis Experiment Methods, edited by Yoshihide Tsujimoto, Separate Volume of Experimental Medicine, Bio Manual Up series, 25 March, 1997 (25.03.97)

Claims 1-3

The subject matters of claims 1-3 do not appear to be novel in view of document 2 cited in the ISR. Human IgM monoclonal antibodies to specifically recognize HIV-infected cells and induce apoptosis, and curing agents for HIV infection that contain such antibodies as active ingredients, all described in claims 1-3, are disclosed in document 2 (the claims, [0018] and examples).

Claims 4-7

The subject matters of claims 4-7 appear to involve an inventive step from documents 1-4 cited in the ISR.

2G9 antibody and cell lines producing it, all described in claims 4-7, are neither described nor suggested in documents 1-4 or other relevant documents.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*